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April 19, 2019

VIA E-MAIL

Adam M. Slater, Esquire
Mazie Slater Katz & Freeman, LLC
103 Eisenhower Parkway
Roseland, NJ 07068

Re: In re Valsartan NDMA Products Liability Litigation Case
No. 1:19-md-02875-RBK-JS

Dear Adam:

I write on behalf of the represented Defendants to address Plaintiffs' revised core discovery requests set forth in your letter of April 16, 2019. As explained below, the revised requests do not accord with the concept of "core" discovery outlined by the Court in our conference last Wednesday with Magistrate Judge Schneider, nor do they comply in letter or spirit with Judge Schneider's email communication to the parties on the following day.

I. The Revised Requests Fail to Limit the Categories of Defendants That Will be Required to Produce Core Discovery.

Despite Judge Schneider's directive in his email of April 11 that "the parties should focus on the contamination issues" during the core discovery phase, the Plaintiffs' revised requests are not limited to the API and finished dose manufacturers of valsartan. Many Defendants are distributors, repackagers, wholesalers, and retailers who do not possess information related to the API manufacturing process. To the extent that distributors, repackagers, wholesalers, and retailers are likely to have any information relevant to this litigation, it would relate primarily to the identification of the products sold to retail customers and sales data, not to the Court's contemplated core discovery of the impurities at issue. Thus the non-manufacturer defendants should not be required to respond to core discovery.

Similarly, the revised requests are not limited to matters concerning valsartan. Currently, certain manufacturers have been named as Defendants in this litigation who have recalled only losartan and irbesartan products. As claims involving drugs other than valsartan are not, at this time, included in the scope of this MDL by the Judicial Panel on Multidistrict Litigation, and Plaintiffs have repeatedly suggested that they intend voluntarily to dismiss all such claims, these Defendants should not be required to answer any discovery at this time.[1]

In short, in accordance with the Court's thoughtful guidance, and consistent with our prior correspondence on this issue, our position is that core discovery at this early stage of the litigation should be directed only to the manufacturers of valsartan API and of finished dose valsartan products.

II. Much of the Information Plaintiffs Request Is Contained in the Core Discovery Defendants Have Already Offered to Produce.

From the outset of this litigation, the Court's directive to the parties has been to focus initial discovery efforts on the central issues: (i) how did the impurities potentially arise in the valsartan products; (ii) when did the manufacturer Defendants become aware of the potential impurities; and (iii) what did the manufacturers do in response to learning of the potential impurities? The core discovery documents the manufacturer Defendants have already offered to produce—namely, the ANDA files, Drug Master Files, and FDA correspondence regarding the recalls—thoroughly answer these questions. And while Defendants do not pretend that these documents represent the sum total of relevant or discoverable information in their possession, the reality remains that Defendants' proposal would be more than sufficient to educate Plaintiffs on the fundamental facts at issue in this litigation, to allow for the identification of those entities who should (and should not) be part of this litigation, and to permit merits discovery to proceed in an orderly fashion. Perhaps the strongest indicator of the reasonableness of Defendants' proposed core discovery can be found in the fact that much, if not most, of the information Plaintiffs now request could be found in those documents Defendants have proposed to produce, including:

- The nature and extent of the contamination, including variations from lot to lot or by other demarcations, as applicable, to the extent known and easily produced. (No. 2)

- How and when the contamination of the Valsartan occurred. (No. 3)

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[1] Even if losartan and irbesartan claims are ultimately included in this MDL, these Defendants should not be required to answer discovery, "core" or otherwise, until the JPML issues an order transferring those cases into this MDL. Further, even if Plaintiffs choose to pursue non-valsartan claims, and the JPML orders them to be included in this MDL, the scope of any discovery should be proportionate to the amount of recalled product, especially when some Defendants have small amounts of recalled product (e.g., as little as 78 bottles of product, or less).

- How and when each defendant discovered that the contamination of the Valsartan occurred, and the steps taken in response. (No. 4)

- All results of testing for impurities of API and finished product going back to 2010. (No. 5)

- Any changes to the manufacturing process, from 2010 to the present, including communications with regulatory agencies relative to the changes to the manufacturing process. (No. 6)

- To the extent the manufacturing process was changed from 2010 to the present, all testing or quality assurance reviews, audits, or oversight, in connection with the change, and the results. (No. 7)

- Quality assurance inspection reports or cGMP inspection/audit reports with regard to the manufacturing process. (No. 8)

By way of further illustration, the manufacturers' communications with the FDA address, *inter alia*, "the nature and extent of the contamination" (No. 2), "[h]ow and when the contamination occurred" (No. 3), testing results related to the recalled products (No. 5), how the manufacturers "discovered that the contamination of the [v]alsartan occurred, and the steps taken in response" (No. 4), inspection information (No. 8), and "communications with [FDA] relative to the changes in the manufacturing process" (No. 6). Additionally, the Drug Master Files include information regarding changes to the manufacturing process (Nos. 6 & 7).

Even so, we note our continuing objection to your failure to direct these largely vague requests to specific Defendants, to valsartan (or even to sartans generally), or to a time period that is within the scope of the FDA's investigation (i.e., four years). Indeed, a response to Request No. 5, for example, would result in an expansive amount of information that is unrelated to valsartan, or even ARBs in general, and is irrelevant to this litigation. In addition, *nine years* of testing information and results, including "all documents analyzing such results," would be impossible to compile in a prompt manner, and, ultimately, disproportionate to the needs of this case at any stage of the proceedings.[2] These open-ended, Rule 34-esque requests are the antithesis of the readily identifiable, easily producible categories envisioned by the Court.

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[2] Even if the parties were at a point in this litigation where this information *may* be relevant, Defendants would object to providing this information on the basis of proportionality, as Federal Rule of Civil Procedure 26(b)(2) directs the Court to limit the frequency and extent of discovery permitted by the rules to prevent discovery for which "the burden or expense . . . outweighs its likely benefit, taking into account the needs of the case . . . the importance of the issues at stake . . . and the importance of the proposed discovery in resolving the issues."

Because the core discovery documents that the manufacturer Defendants have offered to produce address the relevant manufacturing processes and the detection of impurities in valsartan API, they will provide information that efficiently advances this litigation. To the extent Plaintiffs demand further information to supplement that provided in Defendants' proposed core discovery categories, this additional production would place an unreasonable burden on the Defendants before many Defendants have even been served and before the Master Complaints have even been filed and are more appropriate for discovery pursuant to Federal Rule of Civil Procedure 34. *See* Manual Complex Lit. § 11.13 (4th ed.) (predisclosure discovery "should not place unreasonable or unnecessary burdens on the parties[.]").

III. Certain of the Revised Core Discovery Requests Fall Outside the Scope of the Court's Articulated Vision of Core Discovery.

Judge Schneider advised that core discovery should encompass an "(1) easily identifiable, (2) unquestionably relevant and not privileged, (3) relatively easy to retrieve, (4) discrete set of 'core' documents." *See also Udeen v. Subaru of Am., Inc.,* No. 18-17334(RBK/JS), 2019 U.S. Dist. LEXIS 40049, at *4-5 (D.N.J. Mar. 12, 2019) (core discovery should "focus on the core issues in the case to assure that *only the most relevant and important discovery* is produced," and should serve to narrow the parties and issues in a case so that the parties do not go "down a rabbit hole" at a later stage in the proceedings) (emphasis added).

A number of Plaintiffs' revised core discovery requests depart from Judge Schneider's guidance and are more akin to requests for production of documents made pursuant to Federal Rule of Civil Procedure 34, a procedure that he has explicitly stated is premature. These include:

- Readily available documentation of the evaluation of the health risks posed by the contamination. (No. 9)

- To the extent easily identifiable and retrievable, (1) the quantity of non-contaminated, and potentially contaminated Valsartan pills sold by any defendant in the United States, (2) the dosages of those pills, and (3) the prices charged. (No. 10)

- The disposition or storage status of all potentially contaminated pills, including those that have and have not been tested. (No. 11)

None of these documents relate to *how* and *when* the impurities at issue were detected in the product manufacturing process. Further, documents responsive to these requests are not "easily identifiable," "relatively easy to retrieve," or "discrete." Though production of some subset of this information may be appropriate once an ESI protocol is in place, the parties have been identified, the master complaints have been filed, and merits discovery is underway, these are not the readily-identifiable and retrievable materials that are intended to be exchanged in core discovery, and the

burden upon Defendants of producing such materials is unduly burdensome at this stage of the litigation.

IV. The Plaintiffs' Revised Core Discovery Requests Improperly Seek Documents Relating to Foreign Regulatory Agencies.

Request No. 1 asks that Defendants produce "[a]ll communications with foreign regulatory authorities with regard to the contamination/impurities at issue in this litigation, including the EU, Canada, India, China, and Israel." The manufacturer Defendants have already at this early stage offered to produce their communications with the FDA relating to the valsartan recalls. Communications with foreign regulators are unnecessary at this point, and are wholly irrelevant to this litigation, which the JPML expressly acknowledged arises out of the FDA's investigation. *See In Re: Valsartan N-Nitrosodimethylamine (NDMA) Contamination Prods. Liab. Litig.*, MDL No. 2875 at 1-2 (J.P.M.L. Feb. 14, 2019) (transfer order) ("This litigation arises out of an ***investigation by the U.S. Food and Drug Administration*** . . ." and "[a]ll actions stem from the same ***FDA investigation and voluntary recall*** announced in July 2018") (emphasis added).

Moreover, this request for communications with foreign regulatory authorities would impose a burden that is disproportionate to the needs of this MDL where no Plaintiff claims to have purchased products outside the United States. *See In re Bard IVC Filters Prod. Liab. Litig.*, 317 F.R.D. 562, 566 (D. Ariz. 2016) (where, as here, "there are no Plaintiffs in this MDL from foreign countries," the Plaintiffs "allegedly were injured in the United States," and "the burden of this foreign discovery would be substantial," "the proposed discovery is not proportional to the needs of the case"). As these communications are not relevant, impose a substantial burden on Defendants, and are not suitable even during full-blown discovery, they are not the "unquestionably relevant" and "relatively easy to retrieve" types of documents that Judge Schneider directed should be the focus of core discovery.

We look forward to discussing these objections with you during the telephonic meet and confer scheduled for April 22 at 10 a.m.

Very truly yours,

Seth A. Goldberg

Seth A. Goldberg

SAG

cc: Lori Cohen, Esq. (*via email*)
Richard Smith, Esq. (*via email*)
Clem Trischler, Esq. (*via email*)
Jessica Priselac, Esq. (*for distribution to all Defendants*)